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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,405	12/18/2001	Chandrika Govardhan	17741-503	5388

7590 11/16/2004

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EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,405	GOVARDHAN ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/13/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group V in the reply filed on August 30, 2004 is acknowledged.

Claims 1-35 are pending. Claims 1-15 and 25-33 withdrawn from further consideration as being drawn to a nonelected invention.

Claims 16-24, 34, and 35 have been examined on the merits.

Drawings

The drawings are objected to because Figures 2-7 are too dark to discern the detail of the crystalline form. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the

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examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

References A17-A19 have not been considered as they do not correspond to a valid U.S. Patent or Patent Application PGPUB number.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following informalities: several typographical errors are present in the specification, specifically spacing between characters. For example, Example 4 recites, "of220 mg/mL", which should recite, "of 220 mg/mL".

Further, Applicants use of braces "[]" is inappropriate, as it is generally reserved for denoting text deletions and/or modifications, which makes it unclear whether it is included in the text or was, or was intended to be, deleted.

Appropriate correction is required.

Inventorship

Claims 16, 17, 19-24, 34, and 35 are directed to essentially the same invention as that of claims 1-6, 13, 22, 24, 26-30, 40, and 53 of commonly assigned Application No. 10/024,701. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

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Claims 16-24, 34, and 35 are directed to essentially the same invention as that of claims 44-56 of commonly assigned Application No. 10/023,517. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16, 17, 19-24, 34, and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 13, 22, 24, 26-30, 40, and 53 of copending Application No. 10/024,701 ('701). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to substantially similar methods of

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preparing crystalline daptomycin lipopeptide, via crystallization from a crystallization solution. Though not relying upon, but in looking to the specifications for support for the methods, it is noted by the Examiner that instant Examples 1-9 (pages 14-17) are substantially identical to Examples 2-8, 11, and 12 of '701 (pages 20-24).

For example, claim 24 is drawn to a method of preparing a crystalline form of daptomycin and daptomycin analogs comprising the step(s) of:

- 1) combining the lipopeptide with a crystallization solution comprising:
 - a) at least one cation,
 - b) at least one polyhydric or low molecular weight alcohol,
 - c) one or more of organic precipitants, pH buffers, low molecular weight alcohols, and detergents.
 - d) an organic precipitant PEG.

Claim 1 of '701 is drawn to a method for preparing daptomycin, comprising the steps of:

- 1) providing an amorphous form of daptomycin; and
- 2) crystallizing from a crystallization solution comprising:
 - a) a salt comprising a mono- or di-valent cation,
 - b) a buffer,
 - c) an organic precipitant, and
 - d) a low molecular weight alcohol.

The claims differ in that the instant claims are silent to the pre-crystallization form, while '701 is drawn to the amorphous form of the starting material. It is the

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Examiner's position that providing amorphous daptomycin will solubilize in solution and be indistinguishable from any other form of daptomycin in solution, and that in practicing each of the claimed methods one would intrinsically form crystalline daptomycin. The instant claims further differ in that '701 lists fewer components of the crystallization solution.

The claims substantially overlap in that they both are methods *comprising* the step(s) which result in crystalline daptomycin and both solutions *comprise* the listed components and do not exclude any of those listed. Further, the instantly claimed invention encompasses and/or is encompassed by the claimed invention of '701. Thus, by practicing one method you would be intrinsically practicing the other.

Claims 16-24, 34, and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44-56 of copending Application No. 10/023,517 ('517). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to substantially similar methods of preparing crystalline or crystal-like daptomycin lipopeptide from amorphous lipopeptide, via crystallization or precipitation from a crystallization solution. Though not relying upon, but in looking to the specifications for support for the methods, it is noted by the Examiner that instant Examples 1-9 (pages 14-17) are substantially identical to Examples 2-8, 11, and 12 of '517 (pages 36-42).

For example, instant claim 34 is drawn to a method for storing daptomycin comprising the steps of:

- 1) preparing daptomycin in crystalline form, and

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2) storing the crystalline lipopeptide.

Claim 44 of '517 is drawn to a method for storing daptomycin, or related lipopeptides, comprising the steps of:

- 1) providing an solution comprising dissolved lipopeptide,
- 2) crystallizing or precipitating from solution,
- 3) collecting and drying the lipopeptide, and
- 4) storing the lipopeptide;

Steps 1-3 of '517 are the method of 'preparing' daptomycin in the crystalline form.

The claims substantially overlap in that they both are methods *comprising* substantially similar step(s) which result in crystalline daptomycin and 'storing' daptomycin. Further, the instantly claimed invention encompasses and/or is encompassed by the claimed invention of '517. Thus, by practicing one method you would be intrinsically practicing the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

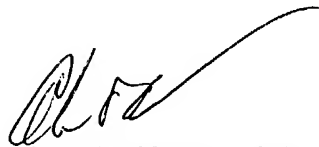
NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-097474. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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